

REMARKS

Claims 1-12, 19-24 and 26-27 are pending in the above-referenced application. Claim 1 has been amended to more distinctly claim that which Applicants regard as their invention. Amended claim 1 is supported by the specification on page 3, lines 29-31.

1. The Rejection Under 35 U.S.C. §103

Claims 1-12, 19-24, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (US 5889002, WO 9726265, and WO 9903861, of record) in view of the Merck Manual of Diagnosis and Therapy (17th ED) (see pages 59-61, PTO-892).

It is asserted in the Office Action that the Nielsen et al. references (US5889002, WO 9726265 and WO 9903861) discloses that the active compounds represented by the general formula I therein which has covered the instant elected species are potassium channel openers and useful in a method of treating various diseases of the central nervous system and the cardiovascular system broadly, e.g. hypertension, heart diseases, coronary heart diseases and especially in methods of treating obesity hyperinsulinemia, insulin resistance and diabetes. These Nielsen references in the Examiner's view further discloses that the range of effective amounts of active compounds therein to be administered is within the instant range.

The Office Action specifically states:

Nielsen et al. does not expressly disclose a method for reducing the consumption of fat-containing food employing the active compounds of Nielsen et al., represented by the general formula I therein. Nielsen et al. does not expressly disclose the instant fat-containing food containing at least 10 kcal% fat.

The Merck Manual of Diagnosis and Therapy (16th ED) teaches that a large amount of fat-containing food to be consumed or a large fat intake is tightly associated with obesity (see 4th paragraph of the right column at page 59), and the complications of obesity are known to be hypertension, hyperinsulinemia, diabetes and coronary heart disease. See the right column of page 61.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the active compounds of Nielsen et al. represented by the general formula I therein, in a method for reducing the

consumption of fat-containing food, and to employ food herein containing from 10-45 kcal% fat.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the active compounds of Nielsen et al., represented by the general formula I therein, in a method for reducing the consumption of fat-containing food since the active compounds of Nielsen, potassium channel openers, are known to be useful in methods of treating hypertension, heart disease, and especially obesity hyperinsulinemia, insulin resistance and diabetes. Moreover, a large amount of fat-containing food to be consumed or a large fat intake is well known to be tightly associated with obesity, and the complications of obesity are known to be hypertension, hyperinsulinemia, diabetes and coronary heart disease according to Merck Manual. Therefore, one of ordinary skill in the art would have reasonably expected that the active compounds of Nielsen would have beneficially therapeutic effect in treating obesity and its complications by reducing the consumption of fat-containing food which may contain at least 10 kcal% fat.

Applicants respectfully traverse the rejection. First, Applicants wish to point out that the claims are directed to **a method for reducing the consumption of fat-containing food and snacking**. This is very different from the method taught in Nielsen et al. (US 5889002, WO 9726265, and WO 9903861). Nielsen specifically teaches using potassium channel openers for reducing obesity by counteracting hyperinsulinemia. Specifically in column 14, lines 1-4, it is stated:

It is expected that potassium channel openers and hence the compounds of the present invention can be used for counteracting the hyperinsulinemia and thereby prevent diabetes and reduce obesity.

Clearly, Nielsen et al. merely suggests that potassium channel openers reduce obesity specifically resulting from hyperinsulinemia. Obesity has a number of causes. Nielsen et al. only suggests the use of potassium channel openers for obesity resulting from hyperinsulinemia. No indication is given in Nielsen that the potassium channel openers can be used to treat other causes of obesity. There is no suggestion in Nielsen et al. that the potassium channel openers of the present invention could be used to reduce consumption of fat containing food and snacking. It was surprisingly found by Applicants that when the animals tested were treated with the present compounds they significantly preferred low fat food instead of fat food (which they normally do prefer). It is specifically stated on page 3, lines 14-26:

Compounds that reduce snacking-behaviour in general and the preference for fat in particular, will have the potential to reduce all-cause mortality in general and in particular morbidity from hypertension, dyslipidemia, type 2 diabetes, coronary heart disease, stroke, gallbladder disease, osteoarthritis, sleep apnea and respiratory problems, and endometrial-, breast-, prostate- and colon cancers. One object of the present invention is to provide compounds, which have a favourable impact on reducing the consumption of fat-derived calories.

SUMMARY OF THE INVENTION

The present invention is based on the discovery that administration of compounds that are potassium channel openers have an effect on the intake of fat food fat, e.g. snack and can be used for reducing or lowering of the intake of fat food, such as e.g. snacking".

The secondary reference, the Merck Manual of Diagnosis and Therapy, is only of general interest and merely discloses one of the causes of obesity. However, no indication is given in either of the prior art references that the potassium channel openers used in the method of the present invention could be used to treat obesity resulting from the consumption of fat containing food.

Applicants do not believe that there would be any motivation to combine Nielsen with the Merck Manual. In Applicants view, a teaching that the potassium channel openers can be used to counteract hyperinsulinemia and thus reduce obesity would not provide any indication that such compounds could be used to reduce obesity by reducing fat consumption and snacking. A finding of obviousness under 35 U.S.C. § 103 requires a determination of the scope and content of the prior art, the differences between the claimed invention and prior art, the level of ordinary skill in the art, and whether the differences are such that the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. *Graham v. Deere*, 383 U.S. 1 (1966). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion that the combination be made. *In re Stencel*, 828 F.2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987).

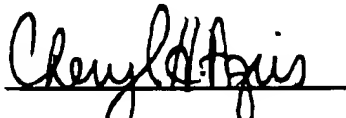
In view of the above arguments and amendments, Applicants assert that the rejections have been overcome. Therefore, Applicants respectfully request the rejections be withdrawn.

2. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Dated: 9/19/03



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